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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,960	11/21/2000	Michael Brines	10165-009-999	6595

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	9

DATE MAILED: 01/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/716,960	Applicant(s) BRINES ET AL.	
	Examiner Regina M. DeBerry	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6,8, drawn to a method comprising administering to a mammal EPO erythropoietin, classified in class 514, subclass 2.

II. Claims 1-6,8, drawn to drawn to a method comprising administering to a mammal EPO receptor activity modulator, class dependent on EPO receptor activity modulator.

III. Claims 1-6,8, drawn to a method comprising administering to a mammal EPO-activated receptor modulator, class dependent on EPO-activated receptor modulator.

IV. Claims 1-8, drawn to a method comprising administering to a mammal nonerythropoietic, class dependent on nonerythropoietic EPO.

V. Claims 1-6,8,9, drawn to a method comprising administering to a mammal erythropoietin analog, classified in class dependent on analog.

VI. Claims 1-6,8,9 drawn to a method comprising administering to a mammal EPO erythropoietin mimetic, class dependent on mimetic.

VII. Claims 1-6,8,9 drawn to a method comprising administering to a mammal EPO erythropoietin fragment, classified in class 514, subclass 12.

VIII. Claims 1-6,8,9 drawn to a method comprising administering to a mammal hybrid erythropoietin fragment, class dependent on hybrid fragment.

IX. Claims 1-6,8-10 drawn to a method comprising administering to a mammal erythropoietin receptor-binding molecule, class dependent on receptor-binding molecule.

X. Claims 1-6,8,9 drawn to a method comprising administering to a mammal erythropoietin agonist, class dependent on agonist.

XI. Claims 1-6,8,9 drawn to a method comprising administering to a mammal renal erythropoietin, classified in class 514, subclass 2.

XII. Claims 1-6,8,9 drawn to a method comprising administering to a mammal brain erythropoietin, classified in class 514, subclass 2.

XIII. Claims 1-6,8,9 drawn to a method comprising administering to a mammal erythropoietin oligomer, classified in class 530, subclass 350.

XIV. Claims 1-6,8,9 drawn to a method comprising administering to a mammal erythropoietin multimer, classified in class 530, subclass 350.

XV. Claims 1-6,8,9, drawn to a method comprising administering to a mammal erythropoietin mutein, classified in class 512, subclass 12.

XVI. Claims 1-6,8,9 drawn to a method comprising administering to a mammal erythropoietin congener, classified in class dependent on congener.

XVII. Claims 1-6,8,9 drawn to a method comprising administering to a mammal naturally occurring form of erythropoietin, classified in class 514, subclass 2.

XVIII. Claims 1-6,8,9 drawn to a method comprising administering to a mammal synthetic form of erythropoietin, classified in class 435, subclass 69.1.

XIX. Claims 1-6,8,9 drawn to a method comprising administering to a mammal recombinant form of erythropoietin, classified in class 435, subclass 69.1.

XX. Claims 1-6,8,9 drawn to a method comprising administering to a mammal a combination thereof, class dependent on the combination of EPO compositions.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. §806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-XX are directed to methods that recite administration to a mammal structurally and functionally distinct compositions. These compositions are not required one for the other, and may not resemble erythropoietin (EPO) both structurally and functionally. A search and examination of all methods in one patent application for administration of the structures of these diverse compositions would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and/or the subject matter is divergent.

Claim 2 is generic to a plurality of disclosed patentably distinct species comprising age-related loss of cognitive function, cerebral palsy, neurodegenerative disease, Alzheimer's disease, Parkinson's disease, Leigh disease, AIDS, dementia, memory loss, amyotrophic lateral sclerosis, alcoholism, mood disorder, anxiety disorder, attention deficit disorder, autism, Creutzfeld-Jakob disease, brain or spinal trauma,

glaucoma, retinal ischemia, or retinal trauma. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claim 3 is generic to a plurality of disclosed patentably distinct species comprising central nervous system tissue and peripheral nervous system tissue. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, separate

search requirements, and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

RMD

RMD
January 4, 2002

ELIZABETH KEMMERER
PRIMARY EXAMINER